

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
Two Militia Drive  
Lexington, MA 02421-4799

Telephone: (781) 861-6240

Facsimile: (781) 861-9540

**FACSIMILE COVER SHEET**

RECEIVED  
OCT 17 2001  
TECH CENTER 1600/2900

**Date:** October 3, 2001

**To:** Ms. Delora Dillard  
Office of Initial Patent Examination (OIPE)  
U.S. Patent and Trademark Office

**Client Code:** 1954.1002-009

**Fax Number:** (703) 305-9822

**From:** David E. Brook, Esq.

**Subject:** Request for Corrected Filing Receipt for Patent Application No.:  
09/924,896  
Attorney Docket No.: 1954.1002-009

Number of pages including this cover sheet: 4Please confirm receipt of facsimile: Yes ☐ No ☐**Comments:**

On the Corrected Filing Receipt that we have received for the referenced application, the title is recorded incorrectly. The correct title is "IL-12 Enhancement of Immune Responses to T-Independent Antigens". Please correct this error and issue a corrected Filing Receipt. A marked up copy of the incorrect Filing Receipt that we received today is enclosed. Also enclosed are copies of the Utility Patent Application Transmittal and page 1 of the Specification, each showing the correct title, for your convenience.

Privileged and Confidential - All information transmitted hereby is intended only for the use of the addressee(s) named above. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any distribution or copying of this communication is strictly prohibited. Anyone who received this communication in error is asked to notify us immediately by telephone and to destroy the original message or return it to us at the above address via first class mail.



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/924,896	08/08/2001	1646	1032	1954.1002-009	11	29	5

CONFIRMATION NO. 3394

## FILING RECEIPT

\*OC00000006798024\*

Anne J. Collins, Esq.  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
Two Militia Drive  
Lexington, MA 02421-4799

COPY

Date Mailed: 09/26/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Dennis W. Metzger, Sylvania, OH;  
Renee M. Buchanan, Toledo, OH;

## Assignment For Published Patent Application

The Medical College of Ohio, Toledo, OH;

## Domestic Priority data as claimed by applicant

THIS APPLICATION IS A CON OF 09/035,594 03/05/1998 PAT 6,303,114

## Foreign Applications

If Required, Foreign Filing License Granted 09/26/2001

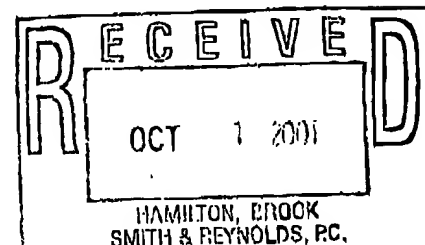
Projected Publication Date: 01/03/2002

Non-Publication Request: No

Early Publication Request: No

Title

RESPONSES  
IL-12 enhancement of immune response to T-independent antigens



## HAMILTON, BROOK, SMITH &amp; REYNOLDS, P.C.

<b>UTILITY PATENT APPLICATION TRANSMITTAL</b> <i>(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))</i>	Attorney Docket No.	1954.1002-009
	First Named Inventor or Application Identifier	Dennis W. Metzger
	Express Mail Label No.	EL 762236460 US

**COPY**Title of  
Invention

IL-12 Enhancement of Immune Responses to T-Independent Antigens

**APPLICATION ELEMENTS**

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents  
Box Patent Application  
Washington, D.C. 20231

1. ☒ Fee Transmittal Form  
(Submit an original, and a duplicate for fee processing)
2. ☒ Specification [Total Pages [ 26 ] ]  
(preferred arrangement set forth below)
- Descriptive title of the invention
  - Cross References to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to microfiche Appendix
  - Background of the Invention
  - Summary of the Invention
  - Brief Description of the Drawings
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
3. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets [ 11 ] ]  
☒ Formal [ ] Informal  
☐ Fig. of the Drawings for Publication - NONE
4. ☒ Oath or Declaration/POA [Total Pages [ 3 ] ]
- a. ☐ Newly executed (original or copy)
- b. ☒ Copy from a prior application (37 C.F.R. 1.63(d))  
(for continuation/divisional with Box 18 completed)  
[NOTE Box 5 below]
- i. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting  
inventor(s) named in the prior  
application, see 37 C.F.R. 1.63(d)(2)  
and 1.33(b).
5. ☒ Incorporation By Reference (useable if Box 4b is checked)  
The entire disclosure of the prior application, from which a  
copy of the oath or declaration is supplied under Box 4b, is  
considered as being part of the disclosure of the accompanying  
application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. ☒ Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)
- a. ☒ Computer Readable Copy
- b. ☒ Paper Copy (identical to computer copy)  
[ 1 ] Pages
- c. ☒ Statement verifying identity of above copies

**ACCOMPANYING APPLICATION PARTS**

8. ☐ Assignment Papers (cover sheet & documents)  
☒ Assignee -  
The Medical College of Ohio  
3000 Arlington Avenue, Toledo, Ohio 43606
9. ☐ 37 C.F.R. 3.73(b) Statement [ ] Power of Attorney  
(when there is an assignee)
10. ☐ English Translation Document (if applicable)
11. ☒ Information Disclosure  
Statement (IDS)/PTO-1449 [X] Copies of IDS  
Citations (AA and  
AV4-AW4)
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
14. ☐ Small Entity [ ] Statement filed in prior application,  
Statement(s) status still proper and desired
15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)
16. ☐ Nonpublication Request (check parent application)
17. ☐ Other:

18. If a **CONTINUING APPLICATION**, check appropriate box and supply the requisite information:

☒ Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: 09/035,594

Prior application information: Examiner: P. Mertz Group Art Unit: 1646

**19. CORRESPONDENCE ADDRESS**

NAME	Anne J. Collins, Esq. HAMILTON, BROOK, SMITH & REYNOLDS, P.C.				
ADDRESS	Two Militia Drive				
CITY	Lexington	STATE	MA	ZIP CODE	02421-4799
COUNTRY	USA	TELEPHONE	(781) 861-6240	FAX	(781) 861-9540

Signature	<i>Anne J. Collins</i>	Date	<i>Aug. 8, 2001</i>
Submitted by Typed or Printed Name	Anne J. Collins	Reg. Number	40,564

ODMA\HODMA\Manage;246376;1  
DEB:AJC:jcc  
08/08/01

PATENT APPLICATION  
Docket No.: 1954.1002-009

-1-

Date: 8-8-01 Express Mail Label No. EL 762236460 US

Inventor(s): Dennis W. Metzger and Renee M. Buchanan  
Attorney's Docket No.: 1954.1002-009

COPY

## IL-12 Enhancement Of Immune Responses To T-Independent Antigens

### RELATED APPLICATION(S)

This application is a continuation of Application No. 09/035,594, filed March 5, 1998. The entire teachings of the above application(s) are incorporated herein by  
5 reference.

### GOVERNMENT SUPPORT

The invention was supported, in whole or in part, by grant R21 AI38380 from the National Institutes of Health. The Government has certain rights in the invention.

### BACKGROUND OF THE INVENTION

5 Non-protein antigens such as polysaccharides and lipids induce antibody responses without the need for T cells and are therefore referred to as T-independent (TI) antigens. However, because of the lack of involvement of T cell help, most TI antigens are relatively poor immunogens. In general, responses to TI antigens consist of  
10 IgM antibodies of low affinity, and do not show significant heavy chain class switching, affinity maturation, or memory. The practical significance of TI antigens is that many bacterial capsular and cell wall polysaccharides belong to this category and are therefore relatively poor at eliciting humoral immunity.

Young children and the elderly are particularly susceptible to life-threatening infections with encapsulated bacteria such as pneumococcus and meningococcus. It has  
15 been estimated by the Centers for Disease Control that in the U.S. per year, *Streptococcus pneumoniae* causes 3,000 cases of meningitis, 50,000 cases of bacteremia, 500,000 cases of pneumonia, and 7 million cases of otitis media (middle ear infection). The World Health Organization has estimated that worldwide, this organism causes 100 million cases per year with 10  
20 million deaths per year. Similarly, *Neisseria meningitidis* is the leading cause of

RECEIVED  
OCT 17 2001  
TECH CENTER 1600/2900

**FILE COPY**

## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov



Bib Data Sheet

CONFIRMATION NO. 3394

<b>SERIAL NUMBER</b> 09/924,896	<b>FILING DATE</b> 08/08/2001 <b>RULE</b>	<b>CLASS</b> 424	<b>GROUP ART UNIT</b> 1646	<b>ATTORNEY DOCKET NO.</b> 1954.1002-009
------------------------------------	---	---------------------	-------------------------------	---

**APPLICANTS**

Dennis W. Metzger, Sylvania, OH;  
Renee M. Buchanan, Toledo, OH;

**\*\* CONTINUING DATA \*\*\*\*\***

THIS APPLICATION IS A CON OF 09/035,594 03/05/1998 PAT 6,303,114

**\*\* FOREIGN APPLICATIONS \*\*\*\*\*****IF REQUIRED, FOREIGN FILING LICENSE GRANTED**

\*\* 09/26/2001

Foreign Priority claimed <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	<b>STATE OR COUNTRY</b> OH	<b>SHEETS DRAWING</b> 11	<b>TOTAL CLAIMS</b> 29	<b>INDEPENDENT CLAIMS</b> 5
35 USC 119 (a-d) conditions met <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Met after Allowance				
Verified and Acknowledged Examiner's Signature _____ Initials <i>SK</i>				

**ADDRESS**

Anne J. Collins, Esq.  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
Two Militia Drive  
Lexington, MA 02421-4799

**TITLE**

IL-12 enhancement of immune responses to T-independent antigens

<b>FILING FEE RECEIVED</b> 1032	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	<input type="checkbox"/> All Fees
		<input type="checkbox"/> 1.16 Fees ( Filing )
		<input type="checkbox"/> 1.17 Fees ( Processing Ext. of time )
		<input type="checkbox"/> 1.18 Fees ( Issue )
		<input type="checkbox"/> Other _____
		<input type="checkbox"/> Credit